University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Parents of Minor Subjects

Medical IRB Study # 01-PED-632
Consent Form Version Date: January 30, 2003

Title of Study: Characterization of mucus and mucins in bronchoalveolar lavage fluids from infants with cystic fibrosis

Principal Investigator: Terry L. Noah, MD
UNC-CH Department: Pediatrics

Co-Investigators: Margaret W. Leigh, M.D., George Z. Retsch-Bogart, M.D., C. William Davis, Ph.D.

Sponsor: National Institutes of Health

You are being asked to allow your child to take part in a research study. The investigators listed above are in charge of the study; other professional persons may help them or act for them.

What are some general things you should know about research studies?

Research studies are designed to gain scientific knowledge that may help other people in the future. Your child may not receive any direct benefit from participating. There may also be risks associated with participating in research studies.

Your child's participation is voluntary. You may refuse to allow this participation, or may withdraw your permission at any time, and for any reason, without jeopardizing your family's future care at this institution or your relationship with your doctor. If your child is a patient with an illness, your child does not have to participate in research in order to receive treatment.

Details about this particular study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want your child to participate. You will be given a copy of this consent form. You are urged to ask the investigators named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn how much and what kind of mucus is present in the lungs of infants with cystic fibrosis (CF), before they develop infections. This is important because currently CF physicians do not know whether the excess sticky mucus causes, or results from, infection in the lungs of young children with CF. Finding out the answer to this will help focus further research into new strategies for prevention of early lung disease in CF.

How many subjects will participate in this study?

Your child will be one of approximately 8-10 subjects in this research study.

How long will your child's participation last?

Your child's participation in this study will last for approximately 12 months, and you and your child will be asked to visit UNC Hospitals 3 times during the 12 months. Each time you come, the tests will take about 4 hours.

What will happen if your child takes part in the study?

You and your child will be asked to come to UNC Hospitals for 3 separate visits, the first within the first 6 weeks of life, then repeat visits at about 6 months of age and 12 months of age. At each of these 3 visits, the following will occur:

1. Bronchoscopy and bronchoalveolar lavage (BAL)

You will be asked to bring your child to the anesthesia pre-care area so an anesthesiologist can meet your child, examine him/her and review his/her medical history. You and your child will remain together until it is time for the bronchoscopy. Your child will undergo bronchoscopy either in the Bronchoscopy Lab or the Operating Room. Your child will be given medicine to make him/her sleepy. After your child is sedated, a bronchoscopy will be done. You will be asked to wait in the waiting area during this procedure. After applying medicine to numb the nose and throat (Xylocaine®), a thin tube is inserted through the nose and down into the lower airways. A small amount of sterile salt water (2 teaspoonfuls), is placed into the airways through the tube, and then suctioned out. This process, called bronchoalveolar lavage or "BAL," is done twice, in order to draw up a sample of lung fluid. This procedure will also be repeated in another area of the lung. The study team will videotape your child's airways during the bronchoscopy so the procedure may be viewed by your child's doctor. The bronchoscopy and BAL procedures take about ten minutes. The sample will be analyzed for types of cells, the presence of inflammation or infection. Any specimens of BAL which remain after the completion of the lab tests will be frozen and stored for future research studies involving cystic fibrosis. After the bronchoscopy, nurses will closely check your child until he/she is fully awake. Your child may then be sent home as directed by the doctor.

2. Questionnaire

In addition to your child having a bronchoscopy done, you will be asked to fill out a questionnaire regarding the kinds of respiratory symptoms your child has been having, and what medications he/she is taking.

3. Storage of BAL fluid for future research

Because lung secretions from infants with CF are so valuable for research, if any of the BAL fluid is left over after the research tests are done for this study, it will be stored in a freezer for possible future use in other research studies.

Are there any reasons your child should not participate?

Your child should not participate in this study if any of the following apply to him/her:

1. History of reactions to or problems with anesthesia or sedation.
2. History of hemoptysis (coughing up blood).
3. History of anemia (low red blood cell count) or thrombocytopenia (low platelet count).
4. Acute respiratory infection or pulmonary exacerbation within 14 days prior to bronchoscopy.
5. Administration of any investigational drug within 30 days prior to today's visit.

What are the possible risks or discomforts?

This study might involve the following risks and/or discomforts for your child:

- Bronchoscopy can cause some irritation of the walls of the nose, throat or bronchial passage. If this occurs, it can cause some bleeding, coughing, or wheezing (happens in 1-2% of patients). Leakage of air through the bronchial wall and lung collapse can also occur but it is much rarer (less than 1%). These complications are minimized by using a very small bronchoscope (1/8 inch wide) and having the procedure done only by experienced bronchoscopists. The study doctors are very experienced at doing this procedure.

- The bronchoscope will partially block the breathing passage while the procedure is being done. In some cases this can make breathing difficult, but your child's breathing and oxygen level will be constantly monitored during the procedure. If he/she has difficulty breathing the procedure will be interrupted or cancelled.

- Insertion of the bronchoscope causes a risk of infection in the lung. The risk of this is very small (less than 1%) because the bronchoscope is sterile, although the bronchoscope may transfer infection from the nose to the lung.

- Bronchoscopy can cause a transient (temporary) slowing of the heart rate in 1-2% of cases. This can occur even if the child's oxygen level is kept high.

- Bronchoalveolar lavage (BAL) can cause transient fever during the 24 hour period following the procedure. This is seen more commonly in young children only when there is a significant amount of inflammation already present in the airways. Fever after bronchoscopy (BAL) is treated with acetaminophen (Tylenol®).

- The sedative medications given to make your child sleepy and comfortable during the bronchoscopy can occasionally cause his/her breathing to become slow or shallow. This will be monitored closely throughout the procedure with both monitors and direct observation of your child, in the same way as it is done routinely whenever bronchoscopy is done in children for non-research purposes.

In addition, there may be uncommon or previously unrecognized risks that might occur.

What are the possible benefits?

As part of this study, we will be obtaining cultures from your child's lungs. Bronchoscopy (BAL) is the only procedure available to obtain reliable cultures from the lower airway of young patients with CF. If your child has an unsuspected pulmonary infection, these results may be useful to your child's doctor as they may assist him/her in choosing appropriate antibiotic therapy. This research is designed to gain knowledge that might help CF patients in the future. We hope this study gives us new information about lung mucus in CF, which would aid in the development of new treatments for CF.

What if we learn about new risks during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation.

How will your family's privacy be protected?

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-CH will take all steps allowable by law to protect the privacy of personal information.

Your privacy will be maintained by assigning a code to your child's BALF specimen and your questionnaire. Your child's name will not appear in any publication resulting from this research.

A copy of this consent form will be placed in your child's medical record. This will allow the doctors caring for your child to obtain information about what procedures he/she is receiving in the study and treat him/her appropriately, if he/she has other health problems or needs during the study.

Will you or your child be paid for participating?

Your child will receive $350 for completing this study**.** If he/she does not complete the study, his/her compensation will be prorated as follows: $100 for each bronchoscopy completed. (An additional $50 will be given upon completion of the entire study)

You will receive $200 for completing this study. If you do not complete the study, your compensation will be prorated as follows: $50 for each questionnaire completed. (An additional $50 will be given upon completion of the entire study). You will also be compensated for travel at the rate of $0.33 per mile, and parking will be free in the hospital parking deck.

Will it cost you anything if your child participates?

The costs of this research will be paid by the sponsor. There will be no costs to you for participating.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being compensated by the sponsor for conducting the study. The researchers do not, however, hold a direct financial interest in the sponsor or the outcome of the study.

What will happen if your child is injured by this research?

All types of research involve possible risk, some including the risk of personal injury. In spite of all precautions, your child might develop complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment, but any costs associated with the treatment will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to compensate you for any such complications or injuries, or for related medical care**. You may contact the principal investigator, Dr. Noah, at XXXXXXXXXX if you have any concerns related to possible bronchoscopy-related complications for your child; if he is not available, you may contact the Pediatric Pulmonologist on call at XXXXXXXXX.** You do not waive any of your legal rights by signing this form.

What if you want to stop before your child's part in the study is complete?

You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child's participation at any time. This could be because he/she has had an unexpected reaction, because you have failed to follow instructions, or because the entire study has been stopped.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have further questions, or if a research-related injury occurs, you should call Dr. Terry L. Noah, M.D. at XXXXXXXXXX .

What if you have questions about your child's rights as a subject?

This research has been reviewed and approved by the Committee on the Protection of the Rights of Human Subjects (Medical IRB) at the University of North Carolina at Chapel Hill. If you have any questions or concerns regarding your child's rights as a research subject, you may contact the Chairman of the Committee at XXXXXXXXXX.

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Parent's Agreement:

I have read the information provided above. I voluntarily agree to allow my child to participate in this study.

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Printed Name of Research Subject (Child)

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Signature of Parent Date

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Printed Name of Parent

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Signature of Parent Date

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Printed Name of Parent

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent